

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

In re:	)	
PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	
	)	Civil Action No. 01-12257-PBS
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	)	Subcategory No. 06-11337
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	
<i>United States ex rel Ven-A-Care of the</i>	)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>	)	Hon. Patti B. Saris
<i>Schering-Plough Corporation and</i>	)	
<i>Warrick Pharmaceuticals Corporation</i>	)	
Civil Action No. 09-CV-10547	)	
 <i>United States ex rel Ven-A-Care of the</i>	)	
<i>Florida Keys, Inc.v. Schering Corporation,</i>	)	
<i>Schering-Plough Corporation and</i>	)	
<i>Warrick Pharmaceuticals Corporation</i>	)	
Civil Action No. 00-10698	)	

**COMMONWEALTH OF MASSACHUSETTS' MEMORANDUM  
IN SUPPORT OF ITS MOTION TO INTERVENE FOR  
THE LIMITED PURPOSE OF OBJECTING TO THE  
VEN-A-CARE/SCHERING/WARRICK SETTLEMENT AGREEMENT**

**Introduction**

The Schering/Warrick defendants<sup>1</sup> and the Relator<sup>2</sup> have jointly filed a Settlement Agreement and Release. (Dkt. No. 6173-2) and a proposed Order Approving Settlement and Dismissal with Prejudice (Dkt. No. 6173-3), which purport to resolve not only the Schering/Warrick defendants' liability in these two cases, but also improperly seek to resolve some or all of their liability to the Commonwealth of Massachusetts (the "Commonwealth"), other states and the United States. The Commonwealth seeks to intervene in these cases to

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<sup>1</sup> The "Schering/Warrick" defendants are Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation.

<sup>2</sup> The Relator is Ven-A-Care of the Florida Keys, Inc.

oppose the Settlement Agreement and the proposed Order. The Commonwealth urges the Court to reject the Settlement Agreement and proposed Order which have been filed, and to insist instead that Settlement Agreement and Order be revised to reflect what is actually being settled, namely the Schering/Warrick defendants' liability for misconduct effecting the CA and FL Medicaid programs only (both federal and state share), as to Warrick albuterol drugs only.

### **Factual Background**

The Relator has two federal False Claims Act qui tam actions pending before this Court relating to the Schering/Warrick defendants. The Massachusetts Civil Action (C.A. No. 00-10698) was originally filed in this Court on April 10, 2000 against numerous defendants including the Schering/Warrick defendants. The United States filed a Notice of Non-Intervention as to the Schering/Warrick defendants on October 29, 2008. The Relator filed an Amended Complaint on December 16, 2008 as to the Schering/Warrick defendants only. The Amended Complaint alleges various federal False Claims Act violations by the Schering/Warrick defendants over the period January, 1996 to at least April, 2005, relating to certain Warrick albuterol drugs only.

The Florida Civil Action (C.A. No. 09-10547-PBS) was originally filed on June 23, 1995 in S.D. Florida. The Schering/Warrick defendants were subsequently added to the case. On January 5, 2009 the claims against the Schering/Warrick defendants were severed from the other defendants and a new Amended Complaint was filed as to the Schering/Warrick defendants only, for claims relating to certain Warrick albuterol drugs only. Both the Massachusetts and the Florida civil actions have been made part of In Re Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456.

On June 26, 2009 the Relator and the Schering/Warrick defendants jointly filed a

Settlement Agreement and Release with the Court, which purports to resolve the two civil actions pending in this Court, as well as separate state False Claims Act actions which the Relator had filed in California and Florida against the Schering/Warrick defendants. Pursuant to this Settlement Agreement the Schering/Warrick defendants are to pay \$55 million into a settlement fund which is to be allocated among the United States, California, Florida, the Relator and Relator's Counsel. In the Settlement Agreement the Relator, purporting to act on behalf of the United States, as well as itself, purports to release the Schering/Warrick defendants:

from any claim, action, suit or proceeding ... that the Relator has asserted or could have asserted on behalf of the United States or on its own behalf arising out of or related to the Covered Conduct or the Covered Drugs ... during the Relevant Period, *including but not limited to the federal share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs.*

Settlement Agreement and Release, Docket No. 6173-2, p.8, ¶5 (emphasis added). The Relator and the Schering/Warrick defendants have conditioned their Settlement Agreement on the Court entering findings of fact and rulings of law that Schering has no liability as to the prices which Schering reported to industry price reporting compendia for its brand name drugs. Id. at pp.8-9, ¶6.

The Commonwealth has a civil action pending in this Court against Warrick for violation of the Massachusetts False Claims Act, among other causes of action. C.A. No. 03-11865-PBS. This civil action was filed on September 23, 2003 and relates to only some of the Warrick drugs at issue in the Massachusetts and Florida civil actions. On December 23, 2008 this Court denied Defendants' Motion for Summary Judgment in the Commonwealth's case. Massachusetts v. Mylan Laboratories, 608 F. Supp. 2d 127 (D. Mass. 2008). The Commonwealth's civil action is one of at least 21 civil actions by states against the Schering/Warrick defendants relating to their

price reporting practices. To date the Schering/Warrick defendants have settled with seven states<sup>3</sup>. Civil actions by 14 states, including Massachusetts, remain pending<sup>4</sup>.

## **ARGUMENT**

### **I. The Commonwealth of Massachusetts Can Intervene In These Cases, As Of Right, Because the Parties' Proposed Settlement Will, As A Practical Matter, Impair and Impede The Commonwealth's Case.**

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Fed.R.Civ.P. 24(a)(2) provides that, on timely motion, the court must permit anyone to intervene who:

Claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposition of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

In order to qualify as an Intervenor as of right under Rule 24(a)(2), a movant must: (1) show it has made a timely motion to intervene; (2) demonstrated a sufficient stake in the ongoing lawsuit; (3) show that resolution of the law suit in its absence threatens to prejudice its interests; and (4) negate the likelihood that some other party can be expected to adequately protect its interests. Negron-Almeda v. Santiago, 528 F. 3d 15, 22 (1<sup>st</sup> Cir. 2008); Geiger v. Foley Hoag LLP Retirement Plan, 521 F. 3d 60, 64 (1<sup>st</sup> Cir. 2008); B. Fernandez & Hnos, Inc. v. Kellogg USA, Inc., 440 F. 3d 541, 544-45 (1<sup>st</sup> Cir. 2006).

Here the Commonwealth can satisfy each of the criteria to intervene as of right. The Commonwealth's motion to intervene is timely. It seeks to intervene only for the limited purpose of objecting to the Settlement Agreement and proposed Order of Dismissal. The parties

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<sup>3</sup> The Schering/Warrick defendants have settlement with the following states for the amounts indicated: AL - undisclosed; AK - \$550,000; CT - \$750,000; NV - \$350,000; OH - \$4.3 million; TX - \$27 million; and MO - \$31 million.

<sup>4</sup> The States or other public entities with civil actions still pending against the Schering/Warrick defendants include AK, CA, FL, HI, IA, ID, IL, KY, MA, MS, NYC and NY counties, PA, SC and WI.

have only recently filed those documents with the Court and even more recently has the Attorney General indicated he objects to the dismissal. The Court has not yet ruled on the matter.

The Commonwealth has a stake in the issues being raised in these law suits. In the Settlement Agreement the Relator purports to release “the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs.” Docket No. 6173-2, p.8, ¶5. The Commonwealth has a civil action pending which relates to the Covered Conduct and the Covered Drugs. Thus, the Relator is purporting to release a portion of the damages which the Commonwealth paid and is attempting to recover.

The Commonwealth’s interests will be adversely affected if the Court approves the parties’ Settlement Agreement and proposed Order. Should the Court approve the Settlement Agreement and Release, as drafted, the Commonwealth will be at risk to be the victim of inconsistent legal rulings. On the one hand, Schering/Warrick can be expected to argue it has settled and paid for that portion of the damages in the Commonwealth’s case for which the federal government reimbursed the Commonwealth. On the other hand, once the Commonwealth makes a recovery in the case, whether by judgment or settlement, it will face a claim by CMS that CMS is entitled to the Federal Medical Assistance Percentage (FMAP) of any such recovery. See 42 U.S.C. § 1396b (d)(3)(A)(“[t]he pro rata share to which the United States is equitably entitled, as determined by the Secretary, … shall be considered an overpayment to be adjusted under this subsection.”).

No existing party in these law suits can be expected to adequately represent the Commonwealth’s interests. Schering/Warrick is a defendant in the Commonwealth’s case and adverse to the Commonwealth’s interests. The Relator has signed the Settlement Agreement which purports to release a portion of the Commonwealth’s claim and can hardly be expected to

protect the Commonwealth's interests. The United States, while not a party in these cases, has been invited by the parties to participate in the review of this Settlement Agreement. While the United States' objections to the Settlement Agreement are similar to the Commonwealth's objections, the interests of the United States and the Commonwealth will diverge if the Court accepts the Settlement Agreement, the Commonwealth makes a recovery against the Schering/Warrick defendants and CMS seeks to obtain a portion of that recovery for the federal treasury.

**II. In The Alternative, The Commonwealth Should Be Granted Permission To Intervene As A Matter of The Court's Discretion.**

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If the Court were to find that the Commonwealth did not qualify to intervene as of right pursuant to Fed.R.Civ. P. 24(a)(2), then the Court should grant the Commonwealth permission to intervene as a matter of discretion, pursuant to Fed.R.Civ. P. 24(b)(1)(B), which provides:

On timely motion, the court may permit anyone to intervene who:

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(B) has a claim or defense that shares with the main action a common question of law or fact.

The Court enjoys "very broad discretion" in deciding whether to allow a movant to intervene pursuant to Rule 24(b). Daggett v. Commission on Government Ethics and Election Practices, 172 F. 3d 104, 113 (1<sup>st</sup> Cir. 1999); Travelers Indem. Co. v. Bastianelli, 250 F.R.D. 82, 85(D. Mass. 2008). The Court is required to consider whether "the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed.R.Civ. P. 24(b) (3).

Here it is clear that the Commonwealth's case shares a number of questions of law and fact with the parties in the main actions. Among others, there are the questions as to whether a Relator can release the federal-share of a state's False Claims Act action relating to Medicaid damages and what constitutes a false WAC price. If the Court were to approve, as drafted, the

Settlement Agreement and Release, the Commonwealth would be prejudiced when issues relating to the federal shares of the damages subsequently arise in the Commonwealth's case. The fact that the Commonwealth's participation in these cases "may be helpful in fully developing the case is a reasonable consideration in deciding on permissive intervention."

Daggert, 172 F.3d at 113.

### **Conclusion**

For the foregoing reasons the Court should grant the Commonwealth permission to intervene in these cases for the limited purpose of objecting to the Settlement Agreement and Release and the proposed Order Approving Settlement and Dismissal With Prejudice.

Respectfully submitted,

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Dated: July 22, 2009

### **Certificate of Service**

I hereby certify I have caused a copy of the foregoing Memorandum to be served on counsel for each other party in these actions by filing it electronically in the Court's CM/ECF system, this 22nd day of July, 2009.

/s/Peter A. Mullin  
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